

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

#### **REMARKS**

Claims 1-3, 5-11, 13-18, 20-24, 26-28, 30-33, 35-36, 38-41, and 43-57 were presented.

Claims 1-3, 5, 27, 28, and 30 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,759,157 to Harada et al. (hereinafter "Harada") in view of U.S. Patent No. 6,524,257 to Ogura et al. (hereinafter "Ogura").

Claims 6, 23, 31, 46, and 50-57 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura, and further in view of U.S. Patent No. 6,450,966 to Hanna (hereinafter "Hanna").

Claims 11, 13, 36, and 38 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura and further in view of U.S. Patent No. 6,405,076 to Taylor et al. (hereinafter "Taylor").

Claims 14-17, 21-22, 39, 40, and 44-45 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura and Taylor and further in view of U.S. Patent No. 4,870,973 to Ueno (hereinafter "Ueno").

Claims 18, 20, 41, and 43 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura and Taylor and Ueno and further in view of U.S. Patent No. 4,592,365 to Georgi (hereinafter "Georgi").

The Office action additionally states that "Claims 6-10, 24, 26, 32, 33, 35, and 47-49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 6-10, 24, 26, 32, 33, 35, and 47-49 define over the art of record in that none of the art teaches or suggest [sic] choosing the deflation measurement when a neonate is detected."

No pending claims are amended at this time.

Claims 1-3, 5-11, 13-18, 20-24, 26-28, 30-33, 35-36, 38-41, and 43-57 are pending.

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

**Response to Rejection of Claims under 35 U.S.C. §103(a)**

**Claims 1-3, 5, 27, 28, and 30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura.**

**1. The combination of Harada and Ogura is made to suggest that measurement during inflation at an inflation rate above 3 mmHg/second would be obvious to one of ordinary skill in the art.**

The combination of Ogura with Harada is argued in the Office Action to be appropriate so as to suggest that the use of an inflation rate of 5 mmHg/sec while making a blood pressure measurement would be obvious to one of ordinary skill in the art. The Office Action asserts that because Harada appears to use the same inflation and deflation rate, and because Ogura teaches a deflation rate of 5 mmHg/sec, it would be obvious to one of ordinary skill to operate a blood pressure measurement device to make blood pressure measurements at inflation rates of 5 mmHg/sec.

**2. Harada explicitly teaches measurement during inflation at an inflation rate of 2-3 mmHg/second.**

The Office Action states at page 2 as regards Harada that “[t]he rate of inflation or deflation is not mentioned.” Applicants note for the record that U.S. Patent No. 5,759,157 to Harada teaches slow inflation at a rate of 2 to 3 mmHg/sec at column 5, lines 42- 48, as shown by the image presented below:

**CPU 28 repeats Step SA1. If a positive judgment is made at Step SA2, the control of CPU 28 goes to Step SA3. At Step SA3, the pressure regulating valve 14 is switched to a slow-inflation position in which the pressure regulating valve 14 permits the pressurized air to be supplied to the cuff 10 at a rate suitable for blood pressure measurements, for example, 2 to 3 mmHg/sec, as shown at point t<sub>2</sub> in FIG. 4.** 45

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

This precise point was made in response to a previous Office Action. Nevertheless, it appears that the Examiner has not taken notice of this explicit statement in Harada, even after Applicants have brought it to the attention of the Examiner.

**3. Harada explicitly teaches a preliminary inflation rate faster than 3 mmHg/second, but not for making a measurement.**

Applicants also note for the record that the same paragraph, at lines 34-38, teaches that "At Step SA1, the pressure regulating valve 14 is placed in a quick-inflation position in which the pressure regulating valve 14 permits a pressurized air to be quickly supplied to the cuff 10 by the air pump 18, as shown at point  $t_1$  in FIG. 4." Therefore, **Harada knows that inflation rates faster than 2-3 mmHg/second can be applied to inflate a blood pressure cuff. However, Harada explicitly elects to slow down the inflation rate to the specified 2-3 mmHg/second during the time he makes his measurement in an inflation interval.**

Fig. 4 of Harada is also indicative that Harada knows to inflate at a rate faster than 2-3mmHg/second and elects not to measure blood pressure under the faster inflation condition.

This precise point was made in response to a previous Office Action. Nevertheless, it appears that the Examiner has not taken notice of this explicit statement in Harada, even after Applicants have brought it to the attention of the Examiner.

**4. Harada is far more expert than one of ordinary skill in the art.**

The Office Action states at page 5 that "Applicant has further asserted that Harada is far more expert than one skilled in the art. **This point is not relevant to the analysis**, as the test is what the art suggest [sic] to one of ordinary skill in the art and not what the art suggests to Harada or Ogura." (emphasis added)

The Office Action at page 2 states with respect to claim 1 that "it would have been obvious to modify Harada to use 5 mmhg/sec as the inflation and deflation rate, as it is merely the use of a well known rate in the art."

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

The argument as to the level of expertise of Harada (and by implication, the level of expertise of Ogura) that was previously presented, and that the Office Action comments on, is incorporated by reference in its entirety.

As regards one of ordinary skill in the art at the time the invention was made (filing date of July 14, 2003), Applicants respectfully submit that even if Harada and Ogura are experts (and therefore not appropriate as “one of ordinary skill in the art”), one of ordinary skill should pay attention to the teachings of Harada and Ogura, as well as the teachings of other contemporaneous publicly available documents that Applicants have the put in the record, including a 2002 American National Standard and a 2003 U.S. Patent based on a PCT application that was published in 2001. Taken together, these teachings indicate:

**first:** that there is not a reason to try a fast inflation rate, if the expert Harada knew of fast inflation rates and gave no indication to try to measure during such rates;

**second:** that there is not a likelihood of success if one were to use a fast inflation rate, because the 2002 American national Standard warns that fast pressure changes lead to errors; and

**third:** that using a fast inflation rate during a blood pressure measurement is not PREDICTABLY going to work, because there is no teaching that measuring during an inflation interval works better, or even as well, if one inflates faster.

Therefore, Applicants respectfully submit that the Office Action incorrectly relies on conclusory and unsupported statements as “proof” of obviousness where there is no basis to suggest that one of ordinary skill who knew of all of the cited teachings would have a reason to try to make a blood pressure measurement using a fast inflation rate, and certainly would not have an expectation of success, or a basis upon which to predict that such an attempt would succeed. *See KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, 82 USPQ2d 1385 (2007). In alternative terms, **the unexpected success of the present Applicants, given the totality of the cited prior art**, in demonstrating that it is possible to make an accurate blood pressure measurement during a period of fast inflation of a blood pressure cuff is itself evidence of non-obviousness.

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

Both Harada and Ogura are trying to solve the same problem as the present invention, namely making an accurate blood pressure measurement in the shortest possible time.

Applicants would like to point out that the argument is an *a fortiori* argument. Applicants also note for the record that inventors are often reluctant to report experiments that fail, while they are quicker to report success.

If experts such as Harada and Ogura, knowing of the possibility of using fast deflation rates, did not describe the use of such fast rates for the making of blood pressure measurements during inflation of a blood pressure cuff (which practice clearly offers the possibility of reducing the total time required to make a blood pressure measurement), then it is logical to suggest that from the cited record, there is no evidence that those experts (Harada and Ogura) suggested or taught that such a practice would work correctly. Given the numerous inventions in the relevant field they have patented, and given that their employer is an active participant in the field, it would be expected that if such a practice HAD occurred to either or both of them, they would have tried to implement it, and if successful in observing that one could accurately measure blood pressure in an oscillometric method during a fast inflation interval, they would have filed for patent coverage because it would have been an improvement over the technology that is cited as known to them. From the cited public record, they did not do so.

The previously presented public information includes U.S. Patent No. 6,602,200 issued August 5, 2003 to Kubo et al. (hereinafter “Kubo”), which was previously cited by Applicants as part of an IDS, and a document submitted by Applicants entitled “Manual, electronic, or automated sphygmomanometers” issued by the Association for the Advancement of Medical Instrumentation as American National Standard ANSI/AAMI SP10:2002 on October 28, 2002 (referred to herein as the “the 2002 American National Standard”). The Kubo patent matured from an application based on International Application No. PCT/JP00/006113 which was published as Publication Number WO01/017427 on March 15, 2001. The instant Office Action appears not to take this prior art into account. See MPEP §2141.02 VI. PRIOR ART MUST BE CONSIDERED IN ITS ENTIRETY, INCLUDING DISCLOSURES THAT TEACH AWAY FROM THE CLAIMS.

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

*A fortiori*, if it did not appear to the experts Harada and Ogura that making a blood pressure measurement during a fast inflation rate was useful, and given the public information that Applicants have provided earlier that even fast deflation rates are to be avoided (let alone fast inflation rates), and that fast inflation rates can be used to determine the parameters needed for a blood pressure measurement to be made upon slow deflation of a blood pressure cuff (but not to measure blood pressure directly during the inflation interval), why would it be obvious to one of ordinary skill at the time the present invention was made that a measurement performed using fast inflation rates would be successful?

As Applicants have previously indicated, Kubo recites at column 2, lines 15-17, that "One object of the invention is to provide an electronic blood pressure meter capable of taking measurements as fast as possible without deteriorating precision." Applicants also indicated that Kubo teaches the use of measurement during a fast inflation rate to determine the parameters needed for a blood pressure measurement to be made upon slow deflation of a blood pressure cuff. The remainder of the argument previously presented will not be repeated here, but is incorporated herein by reference in its entirety.

Applicants previously provided excerpts from the 2002 American National Standard, including page 42, paragraph B.4 Major sources of error, subparagraph Rapid cuff deflation, which describes how and why a deflation rate of 3 mmHg/Sec provides acceptable results, and a deflation rate of 10 mmHg/Sec provides erroneous and unacceptable results. The remainder of the argument previously presented will not be repeated here, but is incorporated herein by reference in its entirety.

##### **5. Ogura teaches a fast inflation rate which is not used for making a measurement.**

The Office Action states at page 5 that "Applicant has further asserted that Ogura only teaches making a measurement at a faster rate during deflation, not inflation. **The examiner agrees**, but notes that since Harada uses the same rate during inflation and deflation, and that **since inflation and deflation measurements are merely inverse measurements of each other**, the teaching would suggest to one skilled in the art to use the faster rate during both inflation and deflation." (emphasis added) As Applicants now show, the conclusory remark

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

that “**since inflation and deflation measurements are merely inverse measurements of each other**” is both unsupported by the cited reference (or by any reference of record) and is incorrect.

Ogura teaches a measurement method that uses four similar measurement techniques, each applied to a different extremity of a human patient. Ogura at column 7, line 57, through column 8, line 17 teaches the use of fast inflation without making a blood pressure measurement during the inflation interval. The remainder of the argument previously presented will not be repeated here, but is incorporated herein by reference in its entirety.

Ogura uses the quick increase of blood pressure to get to the starting point for a deflation measurement, and not at not for the purpose of making a measurement during the inflation rate.

The Office Action provides no evidence to support the conclusory assertion that inflation measurements and deflation measurements are merely inverses of each other. If they were truly inverses, and given that an often-stated purpose of many inventors is to determine a shortest procedure for obtaining an accurate blood pressure measurement, why is it that the standard practice for measuring blood pressure is the initial rapid (but not instantaneous) inflation to a pressure above the systolic pressure, possibly with an interval during which pressure is maintained essentially constant, followed by slow deflation to a pressure below the diastolic pressure, as opposed to what clearly would be at least as short a measurement comprising a measurement made during slow inflation, followed by an essentially instantaneous pressure “dump” that would be expected to be quicker than even a first rapid inflation, and omitting the pressure holding interval?

#### **6. Ogura only teaches making a measurement at 5mmHg/second during deflation, and not during inflation.**

Ogura at column 7, line 57, through column 8, line 17 teaches.

A cuff-pressure changing means 60 controls, in a blood-pressure measuring operation, the air pump 36 and the four pressure control valves 26a, 26b, 26c, 26d, such that the respective pressures  $PC_a$ ,  $PC_b$  of the two upper-arm cuffs 20R, 20L are quickly increased up to a first prescribed target pressure value  $PC_M$  (e.g., about 180 mmHg) and the respective pressures  $PC_c$

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

[sic]  $PC_d$  of the two ankle cuffs 18R, 18L are quickly increased up to a second prescribed target pressure value  $P_{CM}$  (e.g., about 240 mmHg), and **then the pressures  $PC_a$ ,  $PC_b$ ,  $PC_c$ ,  $PC_d$  are slowly decreased at a rate of about 5 mmHg/sec.** (emphasis added)

The remainder of the argument previously presented will not be repeated here, but is incorporated herein by reference in its entirety.

**7. There is no basis for combining Ogura's rate of deflation with Harada's measurement during inflation as "obvious to one of ordinary skill" when both Harada and Ogura knew of higher inflation rates than 2-3 mmHg/second and neither taught or suggested their use during a measurement made in an inflation period.**

Harada is well versed in the field of blood pressure measurements. He taught to make measurements during both inflation and deflation periods. Additionally, Harada plainly taught faster rates of inflation (and deflation) than 2-3 mmHg/second, but elected not to use those higher rates during the measurement of blood pressure.

Ogura teaches making blood pressure measurements at rates of about 5 mmHg/second during deflation. Ogura does not suggest making a measurement during an inflation period at all.

From what Applicants can determine, Ogura and Harada appear to have worked at the same time for the same employer, Colin Corporation, the common assignee of both U.S. Patent Nos. 5,759,157 and 6,524,257.

Ogura should have been on constructive notice of U.S. Patent No. 5,759,157 which issued in 1998, when he filed his priority Japanese filing in March 2001, and when he filed on October 21, 2001 the application that matured into U.S. Patent No. 6,524,257. Nevertheless, neither Harada nor Ogura teach or suggest the use of an inflation rate higher than 2-3 mmHg/second during the making of a blood pressure measurement during an inflation period.

Applicants respectfully submit that in view of the fact that neither of Ogura and Harada teach or suggest making a blood pressure measurement during an inflation period in which the inflation rate is above 2-3 mmHg/second, that **there is clear evidence in the**

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

**public record that teaches away** from such a practice (the 2002 American National Standard), and there is clear evidence that teaches using measurements during fast inflation only to determine parameters to use to make blood pressure measurements during slow deflation (Kubo), then it would not be “obvious to one of ordinary skill in the art” or “obvious to try” making a measurement during an inflation period at a rate above 2-3 mmHg/second based on the disclosures of U.S. Patent Nos. 5,759,157 and 6,524,257, and that there was no predictable expectation of success at the time the present invention was made. Applicants submit that the recent holding of the Supreme Court of the United States in *KSR International Co. v. Teleflex Inc.* does not require a different outcome.

Applicants respectfully submit that hindsight based on the present application is the only basis for proposing the combination of Harada and Ogura to suggest the use of a blood pressure measurement during an inflation period at a rate greater than 3 mmHg/second, e.g., in a regime that neither cited disclosure teaches or suggests, and that other references of equal stature suggest is not useful. Hindsight is an impermissible basis for suggesting a combination.

#### **8. Applicants respectfully traverse the rejection of claims 1-3, 5, 27, 28, and 30.**

In particular, Applicants respectfully traverse the rejections of independent claim 1 and of independent claim 27 as explained below. To the extent that this traversal is successful, there is no further need to argue the patentability of any dependent claim.

Applicants respectfully traverse the rejection previously given as being an improper rejection. Because neither Harada nor Ogura teach or suggest the limitation in claim 1 that recites “a first analysis module, said first analysis module configured to analyze said signal during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated to extract from said signal a systolic blood pressure and a diastolic blood pressure of said vertebrate according to the oscillometric method of measuring blood pressure” nor the limitation in claim 27 that recites “analyzing said signal during an inflation of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated to extract from said signal a systolic

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

blood pressure and a diastolic blood pressure of said vertebrate,” even the combination of Harada and Ogura cannot teach what neither teaches or suggests individually. Accordingly, Applicants respectfully traverse the rejection of independent claim 1 and independent claim 27 based on an improper combination of Harada with Ogura, and further on the basis that, even if a combination of Harada with Ogura were permissible, such combination still fails to teach or suggest the subject matter claimed.

Accordingly, since a limitation of an independent claim is understood to be present in every claim dependent therefrom by 35 U.S.C. §112, fourth paragraph, Applicants respectfully submit that the Examiner has not presented a proper rejection for any claim that depends from claim 1 or from claim 27, if such rejection relies on Harada in view of Ogura for teaching, suggesting or otherwise making obvious a limitation in which a blood pressure measurement is performed and analysis is done “during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated.” Applicant respectfully submits that all of claims 2, 3, 5-11, 13-18, 20-24, and 26 and new claims 50-53 which depend directly or indirectly from independent claim 1 and all of claims 28, 30-33, 35-36, 38-41, and 43-49, and new claims 54-57 which depend directly or indirectly from independent claim 27 are patentable as depending from an allowable base claim, because dependent claims include every limitation of any claim from which they depend.

**Claims 6, 23, 31, 46, and 50-57 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura, and further in view Hanna.**

**A. Response based on the proposition for which Hanna is cited**

Hanna is cited for the proposition that “Hanna detects whether a user is a neonate by comparing a measurement to a stored value and adjusts pressure to avoid injury to the patient.”

It is well known in the blood pressure measurement field to have different cuff sizes for different patients, and one simple way to determine which size cuff is present is for a

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

practitioner to read a marking, such as marking indicating that the cuff is intended to be used in circumference range as measured on a limb of a patient, affixed to the cuff before applying the cuff to a patient.

Hanna only describes determining automatically which of several possible pressure cuffs having one of a range of sizes is attached to a blood pressure measurement machine. The description given by Hanna, at column 4, lines 56-63 teaches:

... In this regard, the inventive apparatus may be provided to identify any given one of a predetermined plurality of inflatable cuffs when interconnected in the pneumatic circuit, wherein each of the predetermined plurality of inflatable cuffs is fixedly and pneumatically interconnected to a corresponding one of a plurality of gas-flow restricting means, each of said gas-flow restricting means being different. (emphasis added)

Hanna then teaches that the maximum pressure that the machine applies depends on which cuff the machine determines to be attached. See Hanna at column 10, lines 19-38.

At column 7, line 47, to column 9, line 67, Hanna describes the cuff identification procedure. In particular, at column 7, lines 54-57, Hanna teaches that “[t]o initiate the procedure, monitor 100 is turned on, a given cuff assembly is secured to a patient (e.g. wrapping cuff 20 about the patient's arm), and cuff assembly 10 is pneumatically interconnected to monitor 100.”

Nowhere does Hanna teach identifying which kind of patient is the subject of a blood pressure measurement, but only which cuff is attached to the monitor. The disclosure of Hanna **tacitly assumes** that the correct size of cuff is applied to a patient. If so, the patient has been identified by the practitioner who attaches the cuff, as one of Hanna's four examples, e.g., a neonate, a child, an average adult or an obese adult. However, if the wrong size or type of cuff is applied by a practitioner, e.g., a neonate cuff applied to a finger of an obese adult, the apparatus Hanna describes has no way to identify whether the patient is any of a neonate, a child, an average adult or an obese adult. Hanna does not describe any system that detects that the wrong size of cuff has been used.

Applicants therefore respectfully submit that because the Office Action has cited Hanna as a reference that teaches a system that identifies a neonate, the Office Action is

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

deficient. **The identification, to the extent that it is correct, is performed by a practitioner before any cuff is attached to the machine,** and the machine identifies the size of the cuff, and determines a maximum pressure to apply with regard to the volume of the cuff that is attached to the machine.

To the extent that the Office Action rejects any of claims 6, 23, 31, 46, and 50-57 on the basis that Hanna purportedly teaches or suggests identifying a neonate, Applicants respectfully traverse the rejection on the basis that Hanna does not so teach or suggest.

**B. Response based on the proposition that Hanna fails to teach or suggest the limitations of claims 1 and 27 missed by Harada and Ogura**

Applicants have presented arguments that Harada and Ogura fail to teach or suggest a limitation in which a blood pressure measurement is performed and analysis is done “during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated.” Hanna is not cited to teach or suggest this missing element.

An electronic search of the text of Hanna as provided on the web site of the United States Patent and Trademark Office fails to disclose any specific reference to or use of a numerical inflation or deflation rate (e.g., there are no references to mmHg/second).

Nowhere does Hanna teach how to make a blood pressure measurement, but only how to determine which of several cuffs is attached to a specific machine. Even the title of Hanna, “Method for non-invasive blood pressure cuff identification using deflation pressure measurements,” indicates that any measurement he does describe is one made on deflation and not on inflation of a cuff. At column 2, lines 20-26, Hanna teaches:

... The method further provides for the obtainment, **during the deflating step,** of at least one gas pressure measurement in the pneumatic circuit. Such gas pressure measurement may then be utilized to identify the inflatable cuff being utilized. (emphasis added)

Accordingly, Applicants respectfully submit that even if Hanna were combined with Harada and Ogura, the limitation in which a blood pressure measurement is performed and

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

analysis is done “during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated” would still not be taught, suggested, or made obvious.

Dependent claims 6, 23, 31, 46, and 50-57 include this limitation by operation of 35 U.S.C. 112, 4<sup>th</sup> paragraph. Applicants respectfully submit that claims 6, 23, 31, 46, and 50-57 are therefore allowable over the combination of Harada, Ogura and Hanna.

**Claims 11, 13, 36, and 38 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura and further in view of Taylor.**

Taylor is cited because it “includes a motion detector and allows blood pressure measurements to continue if the motion is below a threshold (see paragraph 6 in column 9).”

The cited paragraph teaches:

6. The artifact rejector of paragraph 5, wherein the physiologic-event-noise monitor is also constructed to instruct such physiologic-event-measuring equipment during such measurement cycle based upon monitored noise being below a third preselected threshold, to continue such measurement cycle at a preselected rate.

**A. Response based on the proposition that Taylor fails to teach or suggest the limitations of claims 1 and 27 missed by Harada and Ogura**

Applicants have presented arguments that Harada and Ogura fail to teach or suggest a limitation in which a blood pressure measurement is performed and analysis is done “during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated.”

Taylor is not cited to teach or suggest this missing element. Taylor teaches, at column 5, lines 1-13 that:

Also as is known to those skilled in the art, apparatus 10 is usable to measure a subject's blood pressure and heart rate during a suitable measurement cycle. For practicing the present invention, the usual NIBP-cycle may be used as a measurement cycle in the practice of the present invention. Such cycle includes monitoring and processing pressure-signal information

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

from cuff 16 for a defined range of pulsatile information, i.e. from a suprasystolic pressure (cuff inflated) to below diastolic pressure (cuff deflated preferably gradually). Gradual cuff deflation is preferred because it optimizes patient comfort and promotes accuracy of data measurement because, in stepwise cuff deflation, data occurring during step deflation can be lost. (emphasis added)

Accordingly, Applicants respectfully submit that even if Taylor were combined with Harada and Ogura, the limitation in which a blood pressure measurement is performed and analysis is done “during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated” would still not be taught, suggested, or made obvious.

Dependent claims 11, 13, 36, and 38 include this limitation by operation of 35 U.S.C. 112, 4<sup>th</sup> paragraph. Applicants respectfully submit that claims 11, 13, 36, and 38 are therefore allowable over the combination of Harada, Ogura and Taylor.

**Claims 14-17, 21-22, 39, 40 and 44-45 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura and Taylor and further in view of Ueno.**

Ueno is cited for the proposition that it “displays a warning when artifact is detected and measurement is stopped (see abstract for example).”

**A. Response based on the proposition that Ueno fails to teach or suggest the limitations of claims 1 and 27 missed by Harada, Ogura and Taylor**

Applicants have presented arguments that Harada, Ogura and Taylor fail to teach or suggest a limitation in which a blood pressure measurement is performed and analysis is done “during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated.”

Ueno is not cited to teach or suggest this missing element. At column 4, line 58, through column 5, line 7, Ueno teaches:

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

When the system is started by pressing a start key not shown in the drawings, the pressurization pump 4 is activated by a control signal from the MPU 9 and the cuff 1 is pressurized (ST 1) until the pressure level reaches a predetermined pressure level which was initially set up by the pressure level set-up means 14. When the cuff pressure has reached this level, the determination result of ST 2 becomes affirmative and the pressurization of the cuff 1 is terminated by stopping the pressurization pump 4 (ST 3). Then, a gradual depressurization of the cuff 1 is started by a control signal from the MPU 9 (ST 4) and a three-second timer (timer #1) is started (ST 5). The subsequently obtained pulse wave data is digitalized by the AD converter 7 and is stored in a memory area for executing the processing of the pulse wave signal (ST 6). This processing of the pulse wave signal in ST 6 is continued for three seconds (ST 7).

Accordingly, Applicants respectfully submit that even if Ueno were combined with Harada, Ogura and Taylor, the limitation in which a blood pressure measurement is performed and analysis is done “during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated” would still not be taught, suggested, or made obvious.

Dependent claims 14-17, 21-22, 39, 40 and 44-45 include this limitation by operation of 35 U.S.C. 112, 4<sup>th</sup> paragraph. Applicants respectfully submit that claims 14-17, 21-22, 39, 40 and 44-45 are therefore allowable over the combination of Harada, Ogura, Taylor and Ueno.

**Claims 18-20 and 41-43 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura and Taylor and Ueno and further in view of Georgi.**

#### A. Response based on the proposition for which Georgi is cited

Georgi is cited for the proposition that “when measurement is stopped due to artifact, measurement can be resumed if the artifact level falls below the threshold within a predetermined time.”

At column 32, lines 1-12, Georgi teaches away from using the oscillometric method of measuring blood pressure in favor of the auscultation (Korotkoff or K-sound) technique:

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

While FIG. 26 may appear to be a justification of the accuracy of the oscillometric method of blood pressure measurement, it is to be understood that the oscillometric technique using the half-peak amplitude points on the pulse amplitude outline are, at best, only approximations in determining systolic and diastolic blood pressures. In this regard, measurements on individual patients can vary widely and provide sufficient data scattering so that it becomes clear that the auscultation technique utilized in the present invention for determining blood pressures is more consistently reliable in providing accurate measurements. (emphasis added)

Since the independent claims of the present application recite using the oscillometric method, it would appear that Georgi is teaching away from that approach. Accordingly, any teachings that he provides should not be used in a system or method according to the present invention.

Because Georgi teaches away from using the claimed systems and methods, it is not obvious to combine the teachings of Georgi with other prior art that uses the oscillometric method or to apply such teachings to a system and method that Georgi disparages.

Applicants respectfully traverse the rejection of claims 18-20 and 41-43 over any combination of art that teaches away from the claimed invention, including any combination that includes Georgi.

**B. Response based on the proposition that Georgi fails to teach or suggest the limitations of claims 1 and 27 missed by Harada, Ogura, Taylor and Ueno**

Applicants have presented arguments that Harada, Ogura, Taylor and Ueno fail to teach or suggest a limitation in which a blood pressure measurement is performed and analysis is done “during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated.” Georgi is not cited to teach or suggest this missing element. Accordingly, Applicants respectfully submit that even if Georgi were combined with Harada, Ogura, Taylor and Ueno, the limitation in which a blood pressure measurement is performed and analysis is done “during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated” would still not be taught, suggested, or made obvious.

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

Dependent claims 18-20 and 41-43 include this limitation by operation of 35 U.S.C. 112, 4<sup>th</sup> paragraph. Applicants respectfully submit that claims 18-20 and 41-43 are therefore allowable over the combination of Harada, Ogura, Taylor, Ueno and Georgi.

**Claims 6-10, 24, 26, 32, 33, 35, and 47-49 were objected to as being dependent upon a rejected base claim**

Claims 6-10, 24, 26, 32, 33, 35, and 47-49 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants respectfully submit that a careful count of claims indicates that claims 7-10, 24, 26, 32, 33, 35, and 47-49 have not been rejected *per se* (but claim 6 was rejected). Accordingly Applicants understand the claims objected to are only claims 7-10, 24, 26, 32, 33, 35, and 47-49, and not claim 6. If Applicants are mistaken, Applicants request that the Examiner so indicate.

Applicants respectfully submit that claims 7-10, 24, 26, 32, 33, 35, and 47-49 should be allowable if the claims from which they depend are allowable. In particular, Applicants have respectfully submitted that independent claims 1 and 27 are allowable over the cited art. Since Applicants have argued hereinabove that claims 1 and 6 should be allowable, dependent claims 7-10 which depend from them should equally be allowable. Since Applicants have argued hereinabove that claims 1, 11, and 23 should be allowable, dependent claims 24 and 26 which depend from them should equally be allowable. Since Applicants have argued hereinabove that claims 27 and 31 should be allowable, dependent claims 32 and 33 which depend from them should equally be allowable. Since Applicants have argued hereinabove that claims 27, 36, 44, and 46 should be allowable, dependent claims 47-49 which depend from them should equally be allowable.

Applicants decline at this time to amend claims 7-10, 24, 26, 32, 33, 35, and 47-49, but reserve the right to do so before the next Office Action is issued.

Response to Office Action  
U.S. Serial No. 10/619,380  
Inventor: Whitaker et al.  
Filed: July 14, 2003  
Attorney Docket No: 281-398.01

### CONCLUSION

Applicants respectfully request that the application be reconsidered and that the rejections of pending claims 1-3, 5, 6, 11, 13-18, 20-23, 27-28, 30-31, 36, 38-41, 43-46, and 50-57 and the objections to claims 7-10, 24, 26, 32, 33, 35, and 47-49 be withdrawn. Applicants submit that claims 1-3, 5-11, 13-18, 20-24, 26-28, 30-33, 35-36, 38-41, and 43-57 are now in proper condition for allowance, and request the issuance of a Notice of Allowance at the Examiner's earliest convenience.

If the Examiner believes that communication with Applicants' attorney would be advantageous toward the disposition of this case, the Examiner is requested to call Applicants' attorney at the phone number noted below.

Respectfully submitted,  
**HISCOCK & BARCLAY, LLP**

By:

*Joseph B. Milstein*  
Joseph B. Milstein, Pti. D., Reg. No. 42,897  
200 Friberg Parkway, Suite 3001  
Westborough, MA 01581  
Telephone: (508) 475-6620  
Facsimile: (508) 475-6660

Date: December 13, 2007

Customer No.: **\*72742\***  
**72742**  
PATENT TRADEMARK OFFICE